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Attorney Docket No.: 5600.200-US

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Sandal et al Confirmation No: 1759  
Serial No.: 09/426,340 Group Art Unit: 1655  
Filed: October 25, 1999 Examiner: Johannsen, D.

For: Method For Generating A Gene Library

**AMENDMENT UNDER 37 C.F.R. 1.111**Commissioner for Patents  
Washington, DC 20231

Sir:

This Amendment is being submitted with Applicants' Request for Continued Examination (RCE) under 37 C.F.R. §1.114. Please amend the above-identified application as follows (a marked up version pursuant to 37 C.F.R. 1.21 is attached hereto):

**IN THE CLAIMS:**

Please substitute the following amended claims for the pending claims having the same claim numbers:

- Subst D*
1. (Twice Amended) A method for generating a gene library from an environmental pool of organisms isolated from soil, animal dung, insect dung, insect gut, animal stomach, sea or lake water, waste water, sludge, or sediment, which gene library is enriched in DNA encoding a polypeptide with an activity of interest, which method comprises:
    - a) subjecting the environmental pool of organisms to cultivation under conditions wherein the pool of organisms is enriched in organisms harbouring said DNA; and
    - b) preparing a gene library directly from the enriched environmental pool of organisms.
  2. (Twice Amended) The method of claim 1, wherein the conditions are culturing in a medium that contains a substrate for the gene product encoded by said DNA.

D2 13. (Twice Amended) The method of claim 1, wherein the gene library is enriched in DNA encoding an enzyme of interest.

Sub B2 21. (Twice Amended) A method of selecting a DNA sequence encoding a polypeptide of interest from an environmental pool of organisms isolated from soil, animal dung, insect dung, insect gut, animal stomach, sea or lake water, waste water, sludge, or sediment, which method comprises:

- D3 a) subjecting the environmental pool of organisms to cultivation under conditions wherein the pool of organisms is enriched in organisms harbouring said DNA;  
b) producing gene libraries directly from the enriched environmental pool of organisms; and  
c) screening the libraries of step b) for DNA encoding the polypeptide of interest.

22. (Twice Amended) A method of claim 21, wherein the polypeptide of interest encodes an enzyme.

D4 24. (Twice Amended) The method of claim 21, wherein the polypeptide of interest encodes one of a pectinase, amylase, galactanase, arabinase, xylanase or cellulase.

D5 27. (Twice Amended) The gene library of claim 25, wherein the polypeptide is an enzyme which comprises a pectinase, an amylase, a galactanase, an arabinase, a xylanase or a cellulase.

## REMARKS

Claims 1-19, 21-25 and 27 are pending in the application. Claims 2 and 13 have been amended to address a number of informalities. Claims 1 and 21 have been amended to specify that step b) entails "producing gene libraries directly from the enriched environmental pool of organisms." Claims 21, 22 and 24 have been amended to replace the recitation "the desired gene" with the recitation "the polypeptide of interest" in order to address the rejection alleging lack of proper antecedent basis. Claim 27 has been amended to replace the recitation "DNA" with the recitation "polypeptide" in order to clarify that an enzyme is a polypeptide.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

### I. Objections

Claims 2-4 and 13-16 are objected to for various informalities. In particular, claim 2 is objected to on the basis that the phrase "culturing in a medium contains a substrate" is incomplete, and that the phrase should recite, e.g., "culturing a medium that contains a substrate." Claim 13 is objected on the basis that the term "riched" should be amended to "enriched."

Applicants respectfully submit that these objections are rendered moot by the amendments to claims 2 and 13.

### II. The Rejection of Claims 21-24 under 35 U.S.C. 112

Claims 21-24 are rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite. The Examiner contends that the recitation "the desired gene" lacks proper antecedent basis.

Claim 21 has been amended to address the alleged indefiniteness. In particular, claim 21 now recites that step c) entails screening the libraries of step b) for DNA encoding the polypeptide of interest. Claims 22 and 24 have been amended in like manner.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

### III. The Rejection of Claim 27 under 35 U.S.C. 112

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite. The Examiner contends that in the recitation of the phrase "wherein the DNA is an enzyme which comprises," is unclear because this phrase suggests that the "recited DNA is a protein."

Claim 27 has been amended to address the alleged indefiniteness by replacing the term "DNA" with the term "polypeptide."

For the foregoing reasons, Applicants submit that claim 27 overcomes this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **IV. The Rejection of Claims 21-24 under 35 U.S.C. 112**

Claims 21-24 are further rejected under 35 U.S.C. 112, second paragraph, for additional allegations of indefiniteness. In particular, the Examiner contends that, with respect to the recitation "method of selecting a DNA sequence of interest," it is unclear as to what is meant by "selecting a DNA sequence." The Examiner asks whether this language entails detection of a sequence, isolation of a molecule or a mental step of selecting a sequence. The Examiner also alleges that, with respect to step d) of claim 21, it is unclear how a "DNA sequence of interest" would "result from the screening of step c.)"

Applicants respectfully submit that this rejection is rendered moot by the amendments to claim 21. Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **V. The Rejection of the Claims under 35 U.S.C. 103**

Claims 1-7, 13-19, 21-25 and 27 stand rejected under 35 U.S.C. 103 as allegedly being obvious over Duvick et al. in view of Sarkar and Upadhyay. Claims 1-9, 13-19, 21-25 and 27 stand rejected under 35 U.S.C. 103 as being obvious over Duvick et al. in view of Cotta.

Claims 1-8, 10, 12-19, 21-25 and 27 stand rejected under 35 U.S.C. as being obvious over Duvick et al. in view of Jacobsen and Schlein. The substance of each of these obviousness rejections is provided in the prior office actions. The obviousness rejections are respectfully traversed.

Duvick et al. discloses a process of (1) enriching a pool of organisms from an agricultural crop by growing the pool on a substrate (fumonisin, FB1 or FB2), (2) isolating positive organisms through several rounds of selection, (3) making a gene library from a selected organism, (4) cloning and expressing the library in a host cell, (5) selecting a positive clone, and (6) isolating the gene of interest.

In contrast, the claimed invention involves a process of (1) enriching a pool of organisms and (2) making a gene library directly from the enriched pool. However, the Examiner contends that although Applicants argue that the present invention avoids Duvick's time consuming and laborious intensive steps of isolating a positive strain prior to producing the library, such as,

through several rounds of phenotype verification, that because the claims employ the transitional phrase "comprising", the claims are open to performing the time consuming and labor intensive steps. The Examiner further states that the specification teaches that the gene library prepared in step b) may be prepared by any suitable technique known in the art, and this would encompass Duvick et al.

The claims must be construed in light of the specification. In this regard, the specification does not, as alleged by the Examiner, teach the step of preparing a gene library by first isolating a positive strain prior to producing the library. Indeed, the statement in the specification referenced by the Examiner, namely, that "the gene library of step b) may be prepared by any suitable technique known in the art, non-limiting examples of which are described in Example 3 and 4" refers to the technical methods for preparing the library, namely, how an artisan would extract DNA and produce cells which carry this DNA (see, e.g., Examples 3 and 4), not to a step of isolating a positive clone from an enriched pool of organisms. Thus, when properly construed in light of the specification, Duvick et al., alone or in combination with the other cited references, does not teach the step of preparing a gene library directly from the enriched pool.

Accordingly, Applicants submit that the claims overcome the rejections under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of these rejections.

#### VI. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: November 8, 2001

  
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